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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/939,656 | 08/28/2001 | Arthur E. Uber III | P 265228 VI/98-013.FWC.C. | 5530 |
| 21140 | 7590 | 02/26/2008 | EXAMINER DESAUTO, MATTHEW F | |
| GREGORY L BRADLEY MEDRAD INC ONE MEDRAD DRIVE INDIANOLA, PA 15051 | | | ART UNIT 3763 | PAPER NUMBER |
| | | | MAIL DATE 02/26/2008 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/939,656 | UBER, ARTHUR E. | |
| | Examiner | Art Unit | |
| | MATTHEW F. DESANTO | 3763 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 04 December 2007.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 13-18,63-65,67-78,80-88,90 and 91 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 13-18,63-65,67,69-78,80-88,90 and 91 is/are rejected.
- 7) Claim(s) 68 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 13-18, 63-65, 67, 69-78, 80-88, 90 and 91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Orkin et al. (USPN 5,207,642) and further in view of Stewart (USPN 5,163,909).

Orkin et al disclose a fluid delivery system and method comprising delivering a first fluid medium through a reusable per-patient disposable fluid path (Fig 2 for visualization, Col 5 Line 25-Col 6 Line 6, Fig 4, 21), disconnecting a fluid path and disposing the fluid path, followed by connecting a second per-patient disposable fluid path to the reusable path (Col 30 Line 50 - Col 31 Line 60), a pressurizing device (Col 2 Line 55 - Col 3 Line 15 and valve with a tube disposed therein (Claim 17, Figure 3, 15a, 14a for embodiments). Additionally Orkin et al disclose a system with pressurizing devices associated with multiple fluid media (Col 2 Line 55-Col 3 Line 15, Col 19 Line 5 - 60), in particular peristaltic pumps (Col 10 Line 10-60), a mixing apparatus (Col 22 Line 50 - Col 23 Line 10, Figures 14a&b, Element 386), is capable of delivering both contrast and diluents media (Col 4 Line 60 - Col 5 Line 60), an air detector (Col 30 Line 45-70), and an additional pump in the fluid path to deliver the mixture of fluid to the catheter via a catheter connector (Figure 15a and 14a, as well as Fig 4 Element C).

Orkin et al. further discloses in the brief summary that the output fluid-flow conduit is formed from a sterile disposable, single-patient delivery system or tubing set, which after a predetermined period of time the system would be replaced with another similar, sterile disposable delivery system. Orkin et al. never discloses that a second disposable portion would be used and connected to a second patient as well as teaching the step of delivering a second mixture to a second patient.

Stewart discloses the level of skill in the art and the desirability to make the bags, tubes or valves disposable if desired (Column 3, lines 1-10) as well as disclosing a need and background of delivering multiple fluid treatments to multiple patients (Column 1, lines 4-10) .

At the time of the invention it would have been obvious for one of ordinary skill in the art to modify Orkin et al. to read on the claimed invention. The intention of Orkin et al. is to have reusable portions and multiple disposable portions, as described in the background and summary of Orkin et al. Therefore, one of ordinary skill in the art would understand this as well as known the generally procedure of treating patients and replace each catheter set with each new patient. Stewart further supports the need and ability of one in the medical art to make tubes, bags, valves and other elements disposable if desired (Stewart (Column 3, lines 1-10)) since for the most part they are considered reusable since the elements can be reused and the desire to make disposable is up to the user.

The examiner would also like to note, that the step of removing the portion that is inserted into the patient or making that portion disposable is well known in the art

because of the possibility of infection and contamination that can be transferred from one patient to another. Therefore, every medical device that injects fluid into a patient has to have a way to sterilize the element that is inserted into the patient. One well-known method is to use disposable elements that will be inserted into each new patient. Therefore, it is well known to replace each medical device that will be inserted into the patient. The examiner would also like to note that the multiplication of the infuse lines is a mere duplication of parts and has been indicated by the courts as taking only routine skill in the art, which would further support the 103 Rejections made above.

Allowable Subject Matter

3. Claim 68 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

4. Applicant's arguments with respect to claims 13-18, 63-65, 67-78, 80-88, 90, 91 have been considered but are moot in view of the new ground(s) of rejection, but in order to expedite prosecution the examiner will clarify his position on some of the arguments present in the remarks section.

5. With regards to the interpretation of Orkin et al. and whether the tubing is disposable or reusable seems like an obvious modification if Orkin et al. doesn't fully disclose the claimed elements. The examiner understands that there is no structure that prevents or allows the flow paths to be reusable or disposable, and it's only the intended use of the tubing and location of the tube. Therefore, one of ordinary skill in

the art would be able to reuseable a portion if desired or dispose of a portion if desired, depending on if a new mixture was going through or a repeated dose of the same mixture. If there was a structural difference in the tubing then the examiner could understand the different in reusable and disposable, but since this is not the case the examiner maintains his rejection that one of ordinary skill in the art would be able to make something disposable or make something reusable with routine skill.

6. With regards to making and delivering a second mixture, the examiner finds this an obvious modification since the device would be reused on another patient, thus making a second mixture and being used on a second patient, since both prior art references are used in a clinical setting and the purpose of these devices are to be used on a patient and not be disposed of. When making a second mixture and delivering the fluid to a second patient, you are essentially reusing the device, which the examiner believes would be an obvious modification because one of ordinary skill in the art would be able to understand how to set up the device and reuse the device for a second and third and four patient.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW F. DESANTO whose telephone number is (571)272-4957. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick LUCCHESI can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Matthew DeSanto
February 19, 2008

/Matthew F DeSanto/
Primary Examiner, Art Unit 3763